PRODUCT UPDATE

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Sorafenib Is Approved for Use in Renal Cancer

Bayer Pharmaceuticals in West Haven, CT, and Onyx Pharmaceuticals in Emeryville, CA, have received approval from the U.S. Food and Drug Administration (FDA) for Nexavar® (sorafenib) tablets for the treatment of patients with advanced renal cell carcinoma. Little is known about what causes kidney cancer, and the arsenal of chemotherapeutics to use against it is minimal. This is the first approval for a drug to fight kidney cancer in nearly a decade. Nexavar has been shown in trials to delay progression of disease and to prolong progression-free survival. Nexavar is an oral multikinase inhibitor that targets kinases in the tumor cell as well as the tumor vasculature. It fights cancer by targeting tumor growth and tumor angiogenesis (blood vessel growth). Phase III clinical trials are under way to test Nexavar's efficacy against liver cancer and skin cancer. The side-effect profile of Nexavar includes diarrhea, rash, fatigue, hand-foot syndrome, alopecia, nausea, pruritis, hypertension, vomiting, and anorexia. An increased risk for bleeding also may be seen with administration of Nexavar, so patients taking blood thinners should be monitored closely.

A program called Resources for Expert Assistance and Care Helpline (REACH) is available to answer any questions about Nexavar, including treatment, reimbursement, and patient support. Call REACH at 866-NEXAVAR (866-639-2827). Prescribing information is available at www.nexavar.com.

Diabetes Drug May Cause Edema

GlaxoSmithKline in Research Triangle Park, NC, and the FDA notified healthcare professionals about postmarketing reports of new onset and worsening diabetic macular edema for patients receiving rosiglitazone (Avandia®). In most cases, patients also reported peripheral edema. In some cases, the macular edema resolved or improved following discontinuation of therapy, and in one case, macular edema resolved after dose reduction. Macular edema is associated with diabetic retinopathy and is characterized by blurred vision, decreased color sensitivity, and decreased dark adaptation.

Combined Use of Antiemetic May Increase Its Efficacy

The FDA recently expanded its approval of the antiemetic Emend® (aprepitant) (Merck & Co., Inc., Whitehouse Station, NJ), allowing the drug to be combined with another group of antiemetic agents to prevent nausea and vomiting induced by moderately or highly emetogenic drugs, such as high-dose cisplatin. Studies have shown that combined use with other drugs such as Zofran® (ondansetron, GlaxoSmithKline) and dexamethasone have resulted in significantly decreased episodes of nausea and vomiting.

U.S. Food and Drug Administration Issues First Dual Approval

The FDA recently approved Pfizer Inc.'s (New York, NY) oral angiogenesis inhibitor Sutent® (sunitinib) as a treatment for patients with advanced renal cell carcinoma and for patients with gastrointestinal stromal tumors (GISTs) whose disease has progressed or who cannot tolerate Gleevec® (imatinib, Novartis Pharmaceuticals, East Hanover, NJ). Sutent slowed disease progression in patients with GISTs and reduced their mortality risk.

GISTs are uncommon tumors of the gastrointestinal (GI) tract. In the past, some were believed to start in the muscular layer of the GI tract and some were believed to start in nerve cells. Recently, researchers have learned that these cancers are, in fact, not true muscle or nerve tumors. They are believed to start in cells found in the wall of the GI tract, called the interstitial cells of Cajal (ICC). Another possibility is that GISTs start in a very early (primitive) cell in the GI tract, which then can develop into ICC. Most cancers in the GI tract start in glandular cells lining the GI tract. The glandular cells can develop into adenomas (noncancerous tumors of gland cells) or adenocarcinomas (cancers of gland cells). Gastric cancers also can start from squamous cells. GISTs are different from these more common GI tract cancers, in large part because they start in different types of cells. GISTs also are quite different in their prognosis.

Sutent earned accelerated approval for kidney cancer based on evidence that it shrank tumors. Side effects include diarrhea, mouth irritation, skin discoloration, weakness, and altered taste. Pfizer currently is conducting trials to test the drug's ability to treat colorectal, breast, and lung cancers. More information is available at www.sutent.com.

Aromatase Inhibitor May Be Superior to Tamoxifen

Femara® (letrozole, Novartis Pharmaceuticals), an aromatase inhibitor used in women with metastatic breast cancer, has been shown to have superior effect in preventing cancer recurrence, including distant recurrence, than tamoxifen, according to a phase III, double-blind study that compared treatments. Breast cancer is often hormone-receptor positive, meaning that the tumors are stimulated to grow in the presence of circulating estrogen and/or progesterone. Aromatase inhibitors suppress the production of estrogen, whereas tamoxifen blocks estrogen receptors. Ongoing follow-up will continue to determine whether the benefits of Femara over tamoxifen will persist.

Vaccine Appears to Be Effective Against Vaginal Cancers

Merck & Co., Inc., has requested priority review for Gardasil™ vaccine for human papillomavirus (HPV), which has been linked to cervical, vaginal, and labial cancers as well as genital warts. Preliminary studies look promising in regard to cancer prevention. The vaccine is for women who have not been previously infected with HPV, and information about long-term efficacy is under investigation.

New Antifungal Drug Treats Candida Infections

The FDA has approved a new drug, Eraxis™ (anidulafungin) (Pfizer Inc.), for the treatment of Candida infections. Eraxis, a new molecular entity that has not yet been marketed in the United States, is an antifungal drug that is administered via IV and is used to treat Candida infections in the esophagus (candidiasis), bloodstream (candidemia), and other areas, including abdominal abscesses and peritonitis. Candida infections

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are potentially devastating to the oncology population and patients with compromised immune systems, which makes Eraxis an important addition to antifungal therapy. Eraxis was generally well tolerated in clinical studies. The most commonly reported adverse events were mild diarrhea, mild elevations in laboratory tests of liver enzymes, and headache. Additional product information is available at www.eraxisrx.com.

Inhaled Form of Insulin Receives Approval

Many Americans who take insulin injections may have a new alternative. The FDA has approved the first-ever inhaled insulin. Exubera® (insulin human [rDNA origin]) inhalation powder (Pfizer Inc.) for the treatment of adult patients with type 1 and type 2 diabetes is an innovative option for the delivery of insulin. Exubera is a human form of powdered insulin that is inhaled into the lungs through a patient's mouth using a specially designed inhaler. The safety and efficacy of Exubera have been studied in approximately 2,500 adult patients with type 1 and type 2 diabetes. Like any insulin product, low blood sugar is a side effect of Exubera, and patients should carefully monitor their blood sugar regularly. Other side effects seen in clinical trials are cough, shortness of breath, sore throat, and dry mouth. Exubera is not recommended for patients who smoke or have quit smoking within the past six months. The drug is not recommended in patients with asthma, bronchitis, or emphysema. Baseline tests for lung function are recommended after the first six months of treatment and every year thereafter, even if patients have no pulmonary symptoms. For more information, call 800-EXUBERA (800-398-2372).

NEW PRODUCTS

Mastectomy Prosthetic Offers Fit and Function Without Customization

Moldable Lite (Women's Health Boutique, Cypress, TX) is a new prosthetic device for patients after mastectomy that provides a natural look and secure fit without special customization. The prosthetic features a lightweight, air-whipped silicone front and a moldable gel back, which conforms and takes its fit from the chest wall. It allows women to wear multiple undergarments and retain a good fit. Information about the product can be obtained by calling 888-708-9982.

Proton-Beam Therapy Targets Tumors More Precisely

Radiation therapy typically uses protons and electrons to destroy cancer cells, but now protons can deliver cell-killing activity with minimal damage to surrounding tissue. Proton therapy is expected to surpass intensity-modulated radiation therapy and stereotactic radiosurgery with its ability to precisely hit cancer cells. Proton-beam therapy does require a large financial investment and dedication of space. The manufacturer anticipates that generous reimbursement will be available for the radiation procedure. Unlike conventional external-beam radiation therapy, where protons distribute energy across their path, delivering radiation to cancerous and healthy tissue, proton-beam therapy delivers nearly the entire intended radiation dose at the exact depth of tumor, leaving surrounding healthy tissues out of harm's way.

Currently, proton-beam therapy is used in a small number of cancers, specifically eye and prostate cancers. Application to other cancers is expanding, and the benefits are being realized by patients and practitioners across the nation. More information about proton-beam therapy is available at www.proton-therapy.org.

RECALL ALERTS

Glucose Meter May Malfunction and Report Erroneous Results

Roche Diagnostics in Nutley, NJ, has initiated a worldwide voluntary recall of specific Accu-Chek® Aviva Meters because of the potential for an electronic malfunction that can cause the meter to report an erroneous result or shut down and no longer be used.

The recall includes U.S. serial numbers 52500000000–52510999999. In the United States, people with diabetes, healthcare professionals, pharmacists, and distributors have been instructed that if they have a meter with these serial numbers, they should call 888-591-5084 for a product replacement. The recall does not apply to meters with U.S. serial numbers 52511000000 and higher or Accu-Chek Aviva test strips. Information also is available on the Accu-Chek Web site at www.accu-chek.com.

NOTEWORTHY

Video News Program Informs Healthcare Professionals

The FDA has launched Patient Safety News, a monthly online video program that reviews clinically significant recalls, safety alerts, and new product approvals. It also offers important tips on protecting patients. This program for healthcare providers is available at www.fda.gov/psn. The video footage and demonstrations included can be especially helpful to educators in the healthcare industry.

Fertility Organization Educates Patients

With advances in cancer treatment improving patient survival, cancer centers are focusing attention on pre- and post-treatment procedures to preserve fertility and parenthood options. Fertile Hope, a nonprofit organization dedicated to helping patients with fertility concerns, has begun working with National Cancer Institute–designated cancer centers to establish education programs for patients diagnosed with cancer during their reproductive years. Ovarian and testicular radiation therapy, along with chemotherapeutic agents such as the classification of alkylating agents—including cyclophosphamide, mechlorethamine, chlorambucil, and melphalan—cause the greatest damage. Women may face a higher risk of post-treatment infertility than men because cancer therapies can induce premature menopause, whereas sperm production can resume after treatment.

Fertile Hope is an educational resource for patients. It currently is pursuing strategies in the following five areas: research, awareness, education, financial assistance, and support. The organization will strive to advance fertility research, help advance the understanding of fertility risks and preservation options, allow and encourage personal educated decisions, make preservation treatments available regardless of economic status, and help patients cope with important family planning issues. Further information about the nonprofit organization is available at www.fertilehope.org.